
Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI)

1. Purpose and Background

This document provides Veterinary Services (VS) policy for the investigation and communication of a potential Foreign Animal Disease/Emerging Disease Incident (FAD/EDI). Specific communication and operational procedures are provided in the *Foreign Animal Disease Investigation Manual*.

This guidance document represents the Agency's position on this topic. It does not create or confer any rights for or on any person and does not bind the U.S. Department of Agriculture (USDA) or the public. The information it contains may be made available to the public. While this document provides guidance for users outside VS, VS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.

2. Document Status

- A. Valid through 06/05/2017.
- B. This document replaces VS Guidance 12001.1 (October 25, 2012).

3. Reason for Reissuance

Reorganization of Veterinary Services.

4. Authority and References

- A. Authorities (*Code of Federal Regulations* and U.S. Code):

- [7 CFR part 331](#)
- [7 CFR 371.4](#)
- [9 CFR part 53](#)
- [9 CFR part 71](#)
- [9 CFR part 82](#)
- [9 CFR part 94](#)
- [9 CFR part 121](#)
- [9 CFR part 122](#)
- [9 CFR part 161](#)
- [49 CFR 173](#)
- [6 USC 231](#)
- [7 USC 8301 et seq.](#)

B. References:

- [VS Guidance](#) 12000.1, "Foreign Animal Disease Diagnostician Certification Requirements," 1/26/2012
- [Foreign Animal Disease Investigation Manual](#)

C. Definitions:

- 1) An FAD is a terrestrial animal disease or pest, or an aquatic animal disease or pest, not known to exist in the United States or its territories. An EDI is defined as any terrestrial animal, aquatic animal, or zoonotic disease not yet known or characterized, or any known or characterized terrestrial animal or aquatic animal disease in the United States or its territories that changes or mutates in pathogenicity, communicability, or zoonotic potential to become a threat to terrestrial animals, aquatic animals, or humans. An FAD/EDI may involve livestock, poultry, other animals, or wildlife.

In the event of an FAD/EDI investigation involving wildlife, VS will work in close collaboration, communication, and coordination, with State, Tribal, and Federal wildlife agencies with primary jurisdictional authority and subject matter expertise for wildlife.

- 2) A Foreign Animal Disease Diagnostician (FADD) is a Federal or State employed veterinarian who has successfully completed specialized FAD diagnostician training at the National Veterinary Services Laboratories (NVSL) Foreign Animal Disease Diagnostic Laboratory (FADDL) facility at Plum Island, NY; as well as any other specialized training and continuing education as required and administered by VS, including requirements as specified in VS Guidance Document 12000.1.

The Associate Deputy Administrator (ADA) for Surveillance, Preparedness, and Response Services (SPRS), will maintain a national roster of currently available or active FADDs. VS District Directors or designees will maintain District rosters of currently available and equipped FADDs. Assistant District Directors (ADD) will maintain a roster of currently available and equipped FADDs in the jurisdiction(s) for which they are responsible.

5. Audience

VS employees, other affected Federal and State agencies, and affected members of the public.

6. Guidance

The FAD/EDI investigation period is defined as the time from when the investigation is initiated until the time an FAD/EDI is ruled out or confirmed by an FADD field investigation, official NVSL laboratory diagnostic testing or study results, or by official VS case definitions.

A. Objectives

- 1) Provide a veterinary medical assessment that consists of the following:
 - a. Differential diagnosis;
 - b. Classification of investigation, which is necessary to rank and prioritize the differential diagnosis in terms of the magnitude of suspicion for an FAD, in relation to the magnitude of suspicion for an endemic disease or condition; and
 - c. Designation of diagnostic sample priority, which is necessary to rank and prioritize the speed at which diagnostic samples are to be collected, transported, and tested; the FADD, ADD, and State Animal Health Official (SAHO) must concur on the designation of diagnostic sample priority.
- 2) Provide presumptive and definitive diagnostic testing results as rapidly as required by the designation of diagnostic sample priority, in order to rule out or confirm a suspected FAD/EDI agent.
 - a. The FADD, as part of the required site visit or field investigation, will determine if diagnostic sample testing or studies are necessary to rule out or confirm the FAD/EDI. The ADD and SAHO retain the right to request diagnostic sample collection during an FAD/EDI investigation. The ADD and SAHO along with the FADD and NAHLN laboratory director will determine a diagnostic sample submission plan that may include a duplicate set of samples being submitted to the NAHLN lab.
- 3) Ensure the appropriate veterinary medical countermeasures, regulatory actions, and communications are recommended and implemented during the investigation period, as necessary, to prevent and/or mitigate the dissemination of an FAD/EDI agent by interstate or international commerce of animals, animal products, meat, articles, or conveyances. Examples of interstate or international commerce include but are not limited to slaughter or harvest facilities; processing or packing facilities; auction markets; exhibitions or shows; and interstate or international import-export-facilities. The appropriate veterinary medical countermeasures, regulatory actions, and communications will depend on factors such as:
 - a. The epidemiology of the suspected FAD/EDI agent (such as a highly contagious disease).

- b. The clinical and epidemiological findings obtained during the investigation as they correspond to the case definition for the suspected FAD/EDI disease agent (before obtaining presumptive or definitive diagnostic testing results).
- c. The State, Federal, territory, and Tribal jurisdictions and authorities as applied to the specific situation.

B. Critical elements

Critical elements of an investigation include but are not limited to: interviewing persons for incident history; observing clinical signs; performing physical examination of animals; collecting and analyzing epidemiological information; collecting diagnostic samples as necessary; performing necropsy studies as necessary; investigating trace backs and trace forwards of animals, animal products, meat, articles, or conveyances as necessary; recommending and establishing intrastate quarantine as necessary (the authority of the SAHO); and recommending and establishing interstate quarantines during the investigation period as necessary (the authority of the Secretary of Agriculture).

Critical data and information collected during an investigation includes but is not limited to: species affected, clinical signs, lesions observed, herd/flock morbidity and mortality rates, duration of illness, vaccination history, nutritional status, premises conditions, movement history, contact history, evidence or indication of pest or vector, and evidence or indication of zoonotic disease.

C. Classification of investigations and correlation to designation of diagnostic sample priority

1) Classification of FAD/EDI investigations and definitions

Classification of investigation, one of the FAD/EDI investigation objectives, represents the degree of suspicion for an FAD/EDI in relation to the degree of suspicion for an endemic disease or condition. Table 1 presents the three options for the classification of FAD/EDI investigations and their definitions.

Table 1: Classification of FAD/EDI Investigations and Definitions

Classification of Investigations	Definition
High Suspicion	The veterinary medical and regulatory assessments conducted are consistent with an FAD/EDI and are generally inconsistent with an endemic disease/condition.
Intermediate Suspicion	The veterinary medical and regulatory assessments conducted are consistent with an FAD/EDI but are also consistent with an endemic disease/condition.
Low Suspicion	The veterinary medical and regulatory assessments conducted are generally inconsistent with an FAD/EDI and are consistent with an endemic disease/condition.

2) Diagnostic sample priority designations

There are four diagnostic sample designations used during an FAD/EDI investigation. Designations take into account the magnitude of suspicion for a foreign animal disease, as well as the investigation location and consequences related to the speed of the investigation. Designations determine the speed with which sample collection, transportation, and diagnostic study is completed.

Samples designated as Priority 1 are only used for investigations where there is a High Suspicion of an FAD/EDI. Sample collection, transportation, and diagnostic testing are completed using rapid to extraordinary rapid methods. NVSL and National Animal Health Laboratory Network (NAHLN) personnel will perform diagnostic testing and studies as rapidly as possible on sample arrival at the laboratory, whether during regular business hours, nights, weekends, and holidays. NVSL will use overtime as necessary to begin and complete diagnostic testing and studies. The NAHLN laboratories will perform testing as requested. Payment of overtime to NAHLN laboratory personnel will vary by State. Extraordinary collection and transportation methods will be required when the Priority 1 investigation includes a highly contagious FAD/EDI in the differential diagnosis, or when animals, animal products, meat, articles, or conveyances are involved or engaged in interstate or international commerce. This includes but is not limited to animals, animal products, meat, articles, or conveyances currently held in slaughter or harvest facilities, processing or packing facilities, auction markets, exhibitions or shows, and interstate or international import-export facilities. Telephone notification to the National Preparedness and Incident Coordination (NPIC) Center is required for High Suspicion classification.

Priority 2 sample designations are used for investigations where there is an Intermediate Suspicion of an FAD/EDI. Rapid methods must be used to collect, transport, and study diagnostic samples. NVSL and NAHLN personnel will perform diagnostic testing and studies immediately if the samples arrive at the laboratory before the close of the work day. NVSL will use overtime to complete testing and studies. The NAHLN laboratories will perform testing as

necessary. Payment of overtime to NAHLN laboratory personnel will vary by State. Diagnostic samples arriving after the close of the work day will be examined first thing the following day. Diagnostic samples received Saturday will be tested or studied on Saturday only with prior notification and discussion with NVSL and NAHLN laboratory personnel. Telephone notification to NPIC is not required for Intermediate Suspicion classification.

The Priority 3 designation is only used for investigations where there is a Low Suspicion of an FAD/EDI. Investigations with this designation will use routine methods of collection, transport, and diagnostic study. NVSL and NAHLN personnel will perform diagnostic testing and studies in accession order as received. NVSL and NAHLN overtime services will not be used for Priority 3 investigations. The Priority 3 designation is also used for routine surveillance samples. Telephone notification to NPIC is not required for Low Suspicion classification.

The Priority A designation is only used for Intermediate Suspicion of an FAD/EDI classification or Low Suspicion of an FAD/EDI classification when animals, animal products, meat, articles, or conveyances in interstate or international commerce are involved and/or are potentially held, delayed or quarantined pending the results of diagnostic testing or studies for an FAD. It is also used when other known or potential circumstances associated with the investigation indicate it is prudent to obtain diagnostic sample testing results as rapidly as possible. Telephone notification to NPIC is required for Priority A designation. Rapid to extraordinary methods must be employed to collect, transport, and study diagnostic samples. NVSL and NAHLN personnel will perform diagnostic testing and studies as rapidly as possible upon sample arrival at the laboratory, whether during regular business hours, nights, weekends, and holidays. NVSL will use overtime as necessary to begin and complete diagnostic testing and studies. The NAHLN laboratories will perform testing as necessary. Payment of overtime to NAHLN laboratory personnel will vary by State.

Extraordinary transportation methods include the use of hand carried samples, couriers, counter-to-counter services, and complete commercial. Rapid transportation methods include express shipping services such as FedEx® priority overnight. Routine transportation methods include express shipping services such as FedEx® priority overnight (to ensure preservation of diagnostic sample quality).

Table 2 presents the three diagnostic sample priority designations and their associated use and relative speed of sample collection, transportation, and diagnostic study.

Table 2: Diagnostic Sample Priority Designations, Correlation to Classification of Investigations and Speed of Sample Collection, Transportation, and Diagnostic Study

Priority	Investigation Classification	Speed of Sample Collection, Transportation, and Diagnostic Study
Priority 1	High Suspicion	Rapid to extraordinary methods.
Priority 2	Intermediate Suspicion	Rapid methods.
Priority 3	Low Suspicion	Routine methods.
Priority A	Intermediate or Low Suspicion	Rapid to extraordinary methods.

The FADD, ADD, and SAHO must concur on the classification of investigation, and designation of diagnostic sample priority 1, 2, 3, or A. and if a duplicate sample will be collected and sent to an approved NAHLN laboratory in addition to NVSL. If there are questions, concerns, or disagreements regarding the classification of an investigation or the designation of diagnostic sample Priority 1, 2, 3, or A by the FADD, ADD, and the SAHO, then there must be an immediate conference call of the FADD, ADD, and SAHOs with the District Office, NVSL Director, and NPIC staff. The NPIC staff and the District Office will provide the capability to host and coordinate conference calls.

D. Diagnostic case definitions

For more information on diagnostics, please see the *Foreign Animal Disease Investigation Manual*.

The classification and designation of FAD/EDI diagnostic case definitions are the responsibility and authority of the VS Deputy Administrator. Examples of case definitions include “presumptive” and “confirmed” FAD/EDI cases and vary by disease. Refer to the [Animal Health Surveillance SharePoint Site](#) for disease specific case definitions.

E. National Veterinary Services Laboratories (NVSL)

The NVSL safeguards U.S. animal health and contributes to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal-health diagnostic system.

NVSL is the official reference laboratory for FAD/EDI diagnostic testing and study in the United States. NVSL must perform or officially confirm the results of all diagnostic testing and studies related to FAD/EDI investigations in the United States unless otherwise specified by the APHIS Administrator, or as delegated to the VS Deputy Administrator for SPRS.

NVSL has two locations for FAD/EDI diagnostic testing: Ames, Iowa (NVSL Ames) and Plum Island, New York (NVSL FADDL). The transport and shipping of FAD/EDI

diagnostic samples to NVSL Ames or NVSL FADDL by species or suspected disease is found in the *Foreign Animal Disease Investigation Manual*.

Additional information regarding [NVSL](#) can be found online.

F. National Animal Health Laboratory Network (NAHLN)

The NAHLN, created in 2002, is a comprehensive, coordinated, and modernized network of Federal and State animal health laboratories and public agricultural institutions that address emergency biological and chemical threats to animal agriculture and the security of the food supply.

The purpose of the NAHLN is to enhance early detection of FAD agents and newly emerging diseases and to better respond to animal health emergencies (including bioterrorist events) that threaten the nation's food supply and public health.

Personnel in NAHLN laboratories are trained, proficiency tested, and approved to test for multiple FADs of high consequence. With the approval of the SAHO and ADD, FAD samples can be collected in duplicate to send one to the local NAHLN laboratory and the other to NVSL.

A [current roster of the NAHLN laboratories](#) and the testing they are approved to perform can be found online.

The ADD and SAHO along with the FADD and NAHLN laboratory director will determine a diagnostic sample submission plan that may include a duplicate set of samples being submitted to the NAHLN lab.

G. Guidelines for diagnostic testing

However diagnostic testing is completed, NVSL is the official confirmatory laboratory for FAD/EDI testing in the United States unless otherwise specified by the Chief Veterinary Officer (CVO).

- 1) At the discretion of the FADD, ADD, and SAHO in collaboration with the NVSL and NAHLN Laboratory Directors, two sets of diagnostic samples may be obtained.
 - a. The first set of diagnostic samples must always be sent to the appropriate NVSL Laboratory (NVSL Ames or NVSL FADDL).
 - b. The second set of diagnostic samples will be sent to an approved NAHLN laboratory to provide preliminary FAD/EDI diagnostic information before NVSL receives the diagnostic samples.
 - c. If a second set of diagnostic samples cannot be collected, the samples that can be collected must be sent to the appropriate NVSL laboratory, not the NAHLN laboratory.

- 2) In the event of an emergency situation in which the appropriate NVSL Laboratory cannot perform FAD/EDI diagnostic testing, one set of diagnostic samples may be sent to the other NVSL Laboratory, and a second set of samples may be obtained for testing at a NAHLN Laboratory, or sent to another international reference laboratory.
- 3) If the decision is made to submit a second set of diagnostic samples to the NAHLN laboratory, then the ADD and/or SAHO must instruct the FADD to follow the procedures for submitting a second set of diagnostic samples to the NAHLN laboratory. The ADD, SAHO, and/or FADD will notify the NAHLN Laboratory Director if there is a change in the NAHLN laboratory submission plan after the FADD performs the investigation.

If an FAD/EDI outbreak occurs, VS will provide further guidance on diagnostic sample submissions to a NAHLN laboratory.

H. Packaging and labeling

Packaging and labeling of biological substances for shipment requires familiarity with and training in current rules and regulations, which frequently change. Shippers are responsible for proper packaging, marking, labeling, documentation, classification, and identification of each shipment. **Failure to follow regulations can result in substantial financial penalties.**

For more information, please refer to the [“Packing and Labeling Submissions” page](#).

I. State-Federal-Tribal communication and cooperation

The coordinated State-Federal-Tribal response to a potential FAD/EDI requires close communication and cooperation among all stakeholders and jurisdictions. The ADD and the SAHO (or designee) must closely communicate and cooperate on all aspects of an FAD/EDI investigation from initiation to completion.

All FAD/EDI investigations must be initiated by the ADD and/or the SAHO. All FAD/EDI investigations must be assigned by the ADD and/or the SAHO to an FADD. The ADD and/or the SAHO is responsible for initiating a timely investigation of all credible reported or suspected FAD/EDI, including assigning an FADD to complete a site visit or field investigation as a required part of the investigation.

The ADD and/or SAHO will assign an FAD/EDI Case Coordinator(s) to assist with investigation support, communications, and Emergency Management Response System (EMRS) data entry, as required by the location, scale, complexity, or urgency of the investigation.

J. Emergency Management Response System (EMRS)

The EMRS “Routine FAD/EDI Reporting” is a web-enabled database that is the official USDA APHIS database to record all FAD/EDI investigations. The EMRS

database allows automatic email notices to be sent to selected VS personnel when FAD/EDI investigations are initiated in EMRS. This capability enables the field office and NPIC to monitor potential national “clusters” of FAD/EDI investigations on a real-time basis.

The ADD will ensure the EMRS Referral Control Number is assigned and transmitted to the FADD and the SAHO. EMRS must be used for all FAD/EDI investigations.

[EMRS](#) is accessed through the internet and permits approved State, VS, and NAHLN Laboratory personnel access to enter and view investigations from their State or territory. All entries are confidential. EMRS database access at the State or Territory level is controlled and maintained by approval of the ADD and the SAHO.

K. Requirements

Situation reports, spot reports, diagnostic updates, and regulatory assessments will be produced as required by the urgency or complexity of the investigation, or at intervals requested by the Field Office, the VS Associate Deputy Administrator for NPIC, and the VS CVO.

Because of the rapid exchange of information required during FAD/EDI investigations, communications such as phone calls, conference calls, email, and fax must be used when required in addition to the official EMRS database to record information.

7. Inquiries

Any questions regarding these procedures or instructions should be directed to the National Preparedness and Incident Coordination (NPIC) staff.

Main Office Number

(NPIC, One Health Coordination Center, SPRS Logistics Center)

Phone: 301-851-3595

Fax: 301-734-7817

Normal Business

Monday – Friday

8:00 a.m. to 4:30 p.m. ET

NPIC/NVS 24/7 Emergency Answering Service

Foreign Animal Disease Investigations or Emerging Disease Incidents

National Veterinary Stockpile Activation

1-800-940-6524

Acronyms

ADA	Associate Deputy Administrator
ADD	Assistant District Director
APHIS	Animal and Plant Health Inspection Service
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
EDI	emerging disease incident
EMRS	Emergency Management Response System
FAD	foreign animal disease
FADD	Foreign Animal Disease Diagnostician
FADDL	Foreign Animal Disease Diagnostic Laboratory
NAHLN	National Animal Health Laboratory Network
NPIC	National Preparedness and Incident Coordination
NVS	National Veterinary Stockpile
NVSL	National Veterinary Services Laboratories
SAHO	State Animal Health Official
SPRS	Surveillance, Preparedness, and Response Services
USC	United States Code
USDA	United States Department of Agriculture
VS	Veterinary Services